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Irvin C. Harrington, III
FOLEY & LARDNER
35th Floor
2029 Century Park East
Los Angeles, CA 90067-3021

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,723

Applicant(s)

SHAH ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30 and 32-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30 and 32-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/02, 12/20/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 6/19/03, 6/26/03</u> . |

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DETAILED ACTION

In a response of 7/22/04 to a restriction requirement of 6/18/04, applicants canceled claims 1-27 and 31, added new claims 32-70, and elected Group II claims 28-30 with traverse.

5 The traverse does not provide any reasons to support the traverse. The restriction requirement is still considered proper, and is adhered to and made final.

Numbering of the new claims went from claim 44 to claim 49 omitting claims 45-48. Therefore, claims 49-70 have been renumbered
10 as claims 45-66.

Claims examined on the merits are 28-30 and 32-66, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

15 112:

The following is a quotation of the first paragraph of 35 U.S.C.

112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30 and 32-66 are rejected under 35 U.S.C. 112, first
25 paragraph, because the specification, while being enabling for an active protein containing a solidified mixture of glucose oxidase, human serum albumin and a cross-linking reagent, and for use of vapor phase glutaraldehyde to provide non-liquid cross-linking, does not

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reasonably provide enablement for other embodiments within the scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification enables only an active protein and non-liquid cross-linking as set forth above. It would be speculation and unpredictable as to other active proteins and non-liquid cross-linking processes that will provide desired results when carrying out embodiments substantially different from working embodiments disclosed in the specification. The claims must be commensurate in scope with the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 and 32-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is confusing and unclear by requiring a sensor body and an active protein disposed within the sensor body, and not requiring the sensor body to have structure capable of containing the active

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protein. It is suggested the sensor body be required to contain a space within the body for containing the active protein.

In line 1 of claim 29 and where recited in other claims, "hardened" is uncertain as to meaning and scope. Being hardened is relative and subjective, it would be uncertain as when the active protein is hardened and not hardened. It is suggested the active protein be required to be solidified as disclosed in the specification (page 14, line 3 from the last line.

Claims 32-37 are unclear how they further limit the sensor of claim 28. The limitations of the claims are process limitations limiting a process of making the sensor, and do not further define the sensor. If process limitations are required to define the sensor, the sensor should be claimed by a product-by-process claim requiring a complete process for making the sensor, and use the process limitations of claims 32-37 to further limit the process of making the sensor.

In line 2 of claim 32, and where recited in other claims, "non-liquid cross-linking process" is uncertain as to process steps required for the process, and as to the difference in non-liquid and liquid cross-linking. It is suggested the claims require the cross-linking to be by using glutaraldehyde in vapor phase as in claim 35.

Claims 45 and 64 are confusing by not having clear antecedent basis for "the silicone particles".

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In line 2 of claim 46, it is uncertain as to components of a mixture that is a "protein mixture". Is this a mixture of different proteins or is it a mixture of a protein with some other component.

Claims 47-52 are confusing and unclear by using process limitations and/or requiring a non-liquid cross-linking process to further limit the hardened protein material of claim 50 for reasons set forth above in regard to claims 32-37.

Claims 60-62 are unclear as to structure required by reciting "elongated rope-like structure". Being "like" a rope is relative and subjective. Additionally, it is uncertain how a pellet can be like an elongated rope structure. A pellet is solid whereas a rope is woven fibers. Additionally, in claim 65, it is uncertain how the cut pieces differ from the pellet. In line 66, it is uncertain as to how an elongated rope-like structure can be semi-cylindrical since a rope is normally cylindrical.

Claim 40 appears to be a duplicate of claim 30 and should be made dependent on a different claim, or deleted.

Claims 42, 43, 58 and 59 are unclear as to what constitutes the volume on which the percent by weight per volume is based.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-30, 32-41 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark Jr (6,343,225).

The claims are drawn to a biosensor containing an active protein containing glucose oxidase, human serum albumin and a cross-linking reagent. The active protein can be in hardened form. Also claimed is the active protein in the absence of the biosensor.

Clark Jr discloses a glucose sensor containing a cross-linked protein gel containing human serum albumin and glucose oxidase cross-linked with glutaraldehyde (col 9, lines 20-41). The glutaraldehyde may be in vapor form (col 9, line 38).

The gel of Clark Jr is the same as the presently claimed active protein, and the biosensor of Clark Jr containing the gel is the same as the presently claim biosensor. The process conditions of dependent claims will not result in a materially different gel and biosensor than disclosed by Clark Jr.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter

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pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering
5 patentability of the claims under 35 U.S.C. 103(a), the examiner
presumes that the subject matter of the various claims was commonly
owned at the time any inventions covered therein were made absent any
evidence to the contrary. Applicant is advised of the obligation
under 37 CFR 1.56 to point out the inventor and invention dates of
10 each claim that was not commonly owned at the time a later invention
was made in order for the examiner to consider the applicability of 35
U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art
under 35 U.S.C. 103(a).

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being
15 unpatentable over Clark Jr.

The claims require approximately 23-32.5 % (w/v) human serum
albumin.

It would have been a matter of obvious choice to select a
preferred optimum amount of serum albumin to form the gel of Clark Jr.

20 ***Claim Rejections - 35 USC § 103***

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being
unpatentable over Clark Jr in view of Blubaugh Jr et al (5,964,993).

The claims require the active protein to further contain
silicone.

25 Blubaugh Jr et al disclose a glucose sensor containing a cross-
linked protein gel containing serum albumin, Glucose oxidase and

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glutaraldehyde (paragraph bridging cols 7 and 8). Also disclosed is the presence of a silicone compound to facilitate the transport of oxygen to sites of glucose oxidation.

It would have been obvious to include silicone in the protein gel of Clark Jr to obtain its function to facilitate oxygen transport as disclosed by Blubaugh Jr et al. Having the silicone in particle form as in claim 45 would have been a matter of individual preference within the skill of the art.

Claim Rejections - 35 USC § 103

10 Claims 46-62 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark Jr in view of Liston et al (4,891,104).

The claims require the active protein to be hardened and to be in the form of a pellet.

Clark Jr is described above.

15 Liston et al disclose an enzyme electrode containing an enzyme layer formed from a glucose oxidase/bovine serum albumin solution cross-linked with glutaraldehyde to form a bead (col 14, lines 40-46).

It would have been obvious to form the protein gel of Clark Jr as beads as disclosed by Liston et al to obtain the easier handling of beads. Beads can be considered to be pellets. The protein gel of Clark Jr can be considered hardened as compared to the solution from which the gel is formed.

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Claim Rejections - 35 USC § 103

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 46-62 and 66 above, and further in view of Blubaugh Jr et al.

5 The claims require the hardened protein to contain silicone.

Clark Jr and Blubaugh Jr et al are described above.

It would have been obvious to include silicone in the protein gel of Clark Jr to obtain its function to facilitate oxygen transport as disclosed by Blubaugh Jr et al when the gel is in pellet form as
10 suggested by Liston et al. Having the silicone in particle form as in claim 64 would have been a matter of individual preference within the skill of the art.

Claim Rejections - 35 USC § 103

Claims 28-30, 32-43 and 65 are rejected under 35 U.S.C. 103(a) as
15 being unpatentable over Schulman et al (6,498,043 B1) in view of Clark Jr, and if necessary in further view of Avameas et al (4,970,156), Wilkins (5,476,776) or Yamaguchi et al (5,186,808).

The invention and Clark Jr are described above.

Schulman et al disclose a sensor containing in a chamber an
20 enzyme within a gelatinous material such as glutaraldehyde cross-linked albumin (col 11, lines 21-30). The enzyme can be glucose oxidase (col 12, line 42).

It would have been obvious to use human serum albumin as the albumin in the gel material of Schulman et al as suggested by Clark Jr
25 using human serum albumin in the same type of gel material in a

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sensor. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. Avameas et al (paragraph bridging cols 9 and 10 and paragraph bridging cols 17 and 18), Wilkins (col 4, lines 44-51) and Yamaguchi et al (col 10, lines 45-59) further disclose a gel containing glucose oxidase and serum albumin cross-linked with glutaraldehyde, and if needed would have further suggested conditions for preparing the protein gel of Clark Jr.

Claim Rejections - 35 USC § 103

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 28-30, 32-43 and 65 above, and further in view of Blubaugh Jr et al.

The invention and Blubaugh Jr et al are described above.

It would have been obvious to provide silicone in the gel of Schulman et al as suggested by Blubaugh Jr et al to facilitate oxygen transport when containing human serum albumin as set forth above.

Claim Rejections - 35 USC § 103

Claims 46-62 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 28-30, 32-43 and 65 above, and further in view of Liston et al.

The invention and Liston et al are described above.

It would have been obvious to form the protein gel of Schulman et al as a pellet as suggested by Liston et al producing beads, when the gel contains human serum albumin as set forth above.

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Claim Rejections - 35 USC § 103

Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 46-62 and 66 above, and further in view of Blubaugh Jr et al.

5 The invention and Blubaugh Jr et al are described above.

It would have been obvious to provide silicone in the gel of Schulman et al as suggested by Blubaugh Jr et al to facilitate oxygen transport when containing human serum albumin and being in the form of pellets as set forth above.

Conclusion

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
10/8/04